4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No FDA-2012-D-1003]

Small Entity Compliance Guide: What You Need To Know About Registration of Food Facilities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION**:** Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an updated guidance for industry entitled "What You Need To Know About Registration of Food Facilities--Small Entity Compliance Guide." FDA has prepared this guidance to restate the legal requirements pertaining to registration of food facilities in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). Previously, this guidance restated the legal requirements of FDA's food facility registration regulation. This document also served as FDA's Small Entity Compliance Guide for FDA's food facility registration regulation in accordance with the Small Business Regulatory Enforcement Fairness Act. FDA is revising this document to provide guidance intended to help any entity comply with the requirements pertaining to registration of food facilities in the FD&C Act, including the amendments made by FSMA. This document continues to serve as FDA's Small Entity Compliance Guide for FDA's food facility registration regulation. Further, this guidance is intended to set forth in plain language the requirements for registration of food facilities and help small businesses understand the requirements.

DATES: December 17, 2012. Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Compliance, Division of Field Programs and Guidance (HFS-615), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on this guidance to http://www.regulations.gov. Submit written comments on this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the FD&C Act, in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit

additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year and provides FDA with authority to suspend the registration of a food facility in certain circumstances.

FDA has prepared this guidance to restate the legal requirements in section 415 of the FD&C Act. Previously, this guidance restated the legal requirements of FDA's food facility registration regulation at 21 CFR Part 1, Subpart H (§§ 1.225 through 1.243), implementing section 415 of the FD&C Act, as added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This guidance also served as FDA's Small Entity Compliance Guide for 21 CFR Part 1, Subpart H in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). Because section 415 of the FD&C Act was amended by section 102 of FSMA in 2011, FDA is revising this document to provide guidance on section 415 of the FD&C Act, as amended by FSMA. This updated guidance is intended to help any entity comply with the requirements of section 415 of the FD&C Act, including the amendments made by section 102 of FSMA. This document continues to serve as FDA's Small Entity Compliance Guide for 21 CFR Part 1, Subpart H.

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115) as level 1 guidance. Consistent with FDA's good guidance practices regulation, the Agency will accept comments, but it is implementing this guidance document immediately, in accordance with 21 CFR 10.115(g)(2), because the Agency has determined that prior public participation is not feasible or appropriate because the updated guidance document is merely specifying the new requirements of section 102 of FSMA, many of which are already in

effect. This guidance represents the Agency's current thinking on the registration of food facilities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and section 415 of the FD&C Act. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in §§ 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB control number 0910-0502.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: December 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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